REMARKS

Claims 1-13 remain pending in the present application.

Rejection under 35 U.S.C. §102(b) over Reich et al.

Claims 1-13 stand rejected under 35 U.S.C. §102(b) as being anticipated by Reich et al. (U.S. Published Application No. 2002/0042378). The Examiner has taken the position that:

> Reich et al teach a hemostatic composition comprising a continuous liquid phase comprising thrombin and solid phase having polymeric particles and method of making, therefore[.] Note page 3, [0021], all lines wherein a hemoactive composition is defined as having a liquid and solid phase and the solid phase is comprised by the liquid phase. Further a biocompatible polymer is disclosed. Also at page 2, [0012], line 9 thrombin is disclosed as the desirable hemostatic agent. Also the irradiation is disclosed as a conventional sterilization procedure, note the last 4 lines of [0012] at page 2. Therefore, the hemostatic and method of making it are clearly disclosed by the cited reference. Each of the proteins [is] disclosed as well. The steps of the process of combining and mixing and [irradiation] are discussed.
>
> The claims are identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings of the cited reference.

Applicants traverse this basis for rejection and respectfully request reconsideration and withdrawal thereof.

Applicants reiterate their comments in traverse of the application of Reich et al. to reject the present claims, as set forth in their previous response.

Reich et al. invariably disclose dried hemoactive materials comprising a dried, cross-linked biologically compatible polymer. Reich et al. clearly state:

> According to the present invention, hemoactive materials comprise a dried, cross-linked biologically compatible polymer which forms a hydrogel when exposed to blood and a non-cross-linked biologically compatible polymer which solubilizes when exposed to blood. A cross-linked polymer is dispersed in a dried matrix of the non-cross-linked polymer, and the materials are delivered to surgical sites, wounds, and other target regions in tissue which are subject to bleeding or otherwise have blood present ([0012], page 1; emphasis added).

The Reich et al. materials can be formed into sheets ([0012], page 1), powders, pellets, large blocks, plugs, cylinders, tubes, split tubes, or other forms ([0012], page 2). Reich et al. fail to disclose or suggest that their compositions can be in the form of a liquid dispersion, as claimed herein.

The Examiner indicates that liquid dispersions are not claimed herein (outstanding Office Action, page 3, bottom). Applicants agree that the term "liquid dispersion" is not literally in the claim(s); however, upon a fair construction of the claims one must come to the conclusion that Applicants are claiming a solid phase of biocompatible polymer particles which is dispersed in a continuous liquid phase (claim 1). Merriam-Webster's Online Dictionary defines "dispersion" as

> 5.b: a system consisting of a dispersed substance and the medium in which it is dispersed.
> (http://www.merriam-webster.com/dictionary/dispersion)

So while the present claims do not characterize the sterile hemostatic composition as a "dispersion", it is quite clear that the description of the composition itself comports with the definition of a "dispersion"; and that the continuous phase is a liquid. "A rose by any other name would smell as sweet."

Thus, it is clear that the presently claims are directed to a sterile hemostatic composition which is primarily liquid in character. Reich et al. disclose only sterilized solid compositions.

> Usually, the compositions will be in the form of a sheet, typically having a thickness in the range from 1 mm to 25 mm, preferably from 2 mm to 15 mm. Alternatively, the materials can be formed into powders, pellets, large blocks, plugs, cylinders, tubes, split tubes, or other forms which may be conveniently delivered or placed to target tissue sites. (Reich et al., [0012], page 2, middle of paragraph).

The Examiner directs attention to paragraph [0021] for the proposition that Reich et al. disclose sterilizing liquid compositions. However, a fair and complete reading of paragraph [0021] reveals that after forming a liquid composition of the dissolved, non-cross-linked polymer and the dispersed cross-linked polymer, Reich et al. dry the composition to a solid phase form.

> Particles of cross-linked biologically compatible polymer as described above are then suspended in the aqueous medium. The aqueous medium is then dried to form a solid phase comprising the dried polymeric particles in a dry matrix of the non-cross-linked polymer. Lyophilization (freeze-drying) is the preferred drying technique, although air drying, heat-assisted drying, spray drying, molding, and other methods could also be used under certain circumstances. (Emphasis added).

Reich et al. never disclose sterilization of their liquid, intermediate composition; as such, the intermediate, liquid composition cannot comprise "sterile thrombin", as claimed herein, and cannot therefore anticipate the present claims.

> A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art

> reference. Verdegaal Bros. V. Union Oil Co. of California, 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Withdrawal of the rejection is requested on this basis.

Instead, Reich et al. disclose sterilization of "dried polymeric materials".

> Referring now to FIG. 3, kits according to the present invention will comprise a sheet 10 or other form of the dried polymeric material of the present invention, such as pellets 12, plugs 14, or the like. The materials will be formed sterilely or will be sterilized, preferably by terminal sterilization using γ-irradiation, ethylene oxide, electronic beam irradiation, and the like. While still in a sterile form, the materials will be packaged in a sterile package 20, such as a pouch, tube, tray, box, or the like. Instructions for use setting forth a method of placing the material over tissue in the presence of blood, e.g., at a wound, or surgical site, will also be provided as part of the kit. (Paragraph [0041], emphasis added).

Applicants respectfully submit that Reich et al. fails to anticipate the presently claimed invention.

In maintaining the rejection from the prior Office Action, the Examiner states:

> The method of preparing the instant composition does not necessarily require sterilization of the liquid either but sterilization of the whole composition, note instant claim 8, of page 12, line 8. Applicants' claims do not omit sterilization of the composition as a whole at least as the claims read now. (Outstanding Office Action, page 4, middle).

Yes, Applicants do claim sterilization of the "whole composition"; however, the "whole composition" is in the liquid state, i.e. it has a continuous phase of liquid. In part, claim 8 states:

> mixing said liquid comprising said thrombin and said particles under conditions effective to form a continuous liquid phase comprising said thrombin and said particles substantially homogenously dispersed there through, thereby forming a substantially homogeneous hemostatic composition; and
>
> irradiating said substantially homogeneous hemostatic composition with an amount of ionizing radiation and for a time effective to provide a sterile, substantially homogeneous hemostatic composition,...(claim 8, emphasis added).

Thus, it is clear that the "substantially homogeneous hemostatic composition" has a "continuous liquid phase" and comprises thrombin during the actual sterilization step. This Reich et al. fail to disclose.

> [R]ejections under 35 U.S.C. 102 are proper only when the claimed subject matter is identically disclosed or described in "the prior art"...[so as to] direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference...There is nothing in the teachings relied upon by the Patent Office which "clearly and unequivocally" directs those skilled in the art to make this selection nor any indication that [patentee] ever made the selection himself. In re Arkley, Eardley and Long, 172 USPQ 524, 526 (CCPA 1972); emphasis added.

The Examiner's rejection relies upon reading disparate, unrelated portions of the Reich et al. reference together. Such "picking and choosing" is not permitted within the purview of the patent law as to anticipation. Withdrawal of the rejection is requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (14761).

In view of the foregoing, it is respectfully submitted that the present claims are in condition for allowance. Prompt notification of allowance is respectfully requested.

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to contact the undersigned representative at the number set forth below.

Respectfully submitted,

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